Northwell Health℠

Institutional Review Board
FWA #00002505
Office of the Human Research Protection Program
125 Community Drive
Manhasset, NY 11030
Phone: 516-465-1910

The study cannot begin enrollment until you receive Northwell Institutional Approval (IA). Institutional Approval is separate from IRB approval, and will be issued in a separate letter. For IA guidance click here, or visit the HRPP website.

To: Jacqueline Moline, MD
600 COMMUNITY DR
MANHASSET, NY 11030

From: Hallie Kassan, MS, CIP
Director, Human Research Protection Program

Date: March 23, 2018

RE:

IRB #:	18-0225
Protocol Title:	Mesothelioma and Environmental Exposure to Asbestos
Approval Date:	March 23, 2018
Expiration Date:	March 22, 2019

Dear Jacqueline Moline

The above referenced project meets the criteria outlined in 45 CFR 46.110 and 21 CFR 56.110 for EXPEDITED REVIEW and has been approved. The following category(ies) apply(ies) to the project:

45 CFR 46.110 (5): Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

Expedited Approval of this project includes:

1. Application for Chart Review xform submitted to the IRB on: 3/21/2018.
2. This study has been issued a waiver of informed consent and HIPAA authorization.
3. The following study personnel are authorized to participate in the study: Jacqueline Moline, Kristin Bevilacqua, and Maya Alexandri.

The Institutional Review Board will be notified of this action. This study has not been approved for the inclusion of pregnant women, children, or prisoners. If you would like to include these populations, please notify the IRB for further instruction.

The IRB approval expiration date is listed above. As a courtesy, approximately 60 to 90 days prior to expiration of this approval, the Office of the IRB will send an e-mail reminding you to apply for continuing review. Failure to receive renewal notification does not relieve you of your responsibility to provide the Progress Report to the IRB in time for the request to be processed and approved prior to your expiration date. It is your responsibility to apply for continuing review and receive continuing approval for the duration of the study. Lapses in approval should be avoided to protect the safety and welfare of enrolled subjects.

Subject recruitment methods for enrollment are appropriate, there is equitable selection of subjects, and there are provisions to protect and maintain the confidentiality of data and research participants.

Investigators are reminded that research must be conducted in accordance with all applicable Department of Health and Human Services regulations 45 CFR 46, Food and Drug Administration regulations 21CFR 50, 21CFR 56, 21 CFR 812, and the Health Insurance Portability and Accountability Act (HIPAA).

All studies are subject to audits by the Office of Research Compliance and/or Institutional Review Board to confirm adherence to institutional, state, and federal regulations governing research.

NOTE: This approval is subject to recall if at any time the conditions and requirements as specified in the IRB Policies and Procedures are not followed (see next page and web site: http://www.northshorelij.com/body.cfm?ID=2804)

NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
3. Reporting unanticipated problems involving risk to subjects or others.
4. Prior to implementation, any changes made to studies utilizing TAP must have COPP, as well as IRB approval.

IMPORTANT REMINDER: The International Committee of Medical Journal Editors (ICMJE) requires registration of clinical research studies meeting specific guidelines prior to publication. Please see ICMJE requirements for registration of clinical trials at http://www.icmje.org. Our organization account is in the name of the North Shore-Long Island Jewish Health System. To register your trial: http://prsinfo.clinicaltrials.gov. You must register your trial PRIOR TO ENROLLING SUBJECTS.